Food and Drug Administration Center for Food Safety and Applied Nutrition Office of Special Nutritionals

ARMS#

12843

8 - OTHER

PAGE 2

Case Number

CORONER REPORT

CONTINUATION SHEET

(A) LIST AND DESCRIBE ALL PROPERTY SEIZED, WHERE FOUND AND DISPOSITION.

(B) LIST DOCUMENTS: i.e. WILLS, SUICIDE NOTES.

(C) NARRATIVE SECTION: RELATE ALL PERTINENT FACTS OF INVESTIGATION.

(D) IF VEHICLE ACCIDENT: 1. LIST WHETHER DECEASED WAS DRIVER, PASSENGER OR PEDESTRIAN.

2. LIST AGENCY AND OFFICER INVESTIGATING.

A: None

B: None

C: This case was reported by the Staff at

Upon arrival at the Hospital I

learned that the decedent had been transferred from the

1200 hours. The admitting history obtained from

decedent had collapsed after

Accordingly, the decedent was taking an over the counter preparation called "Ripped Fuel" which is described on its label as being a Metabolic Enhancer.

Medical records accompanying the decedent from indicated that the decedent was on a field located at At 1842 hours on 4-6-98 the decedent experienced sudden collapse. She is described as falling face forward onto the ground and in another history taken at the she is described as falling to her knees and then having a seizure and collapsing forward onto the ground. At the time of the collapse, the decedent's activity had been and then taking a couple of steps. The event was witnessed by numerous members of the



PAGE 3

SHERIFF'S DEPARTMENT

Case Number

CORONER REPORT CONTINUATION SHEET

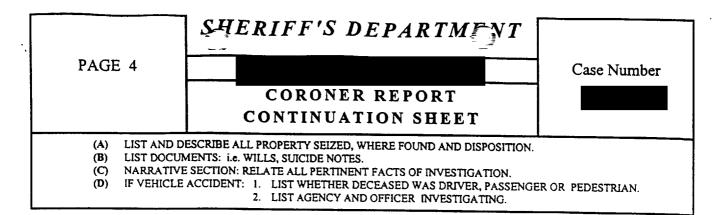
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A coach went to the aid of the decedent immediately and found her to be unconscious and unresponsive. He initiated CPR and continued with resuscitation until relived by paramedics. The decedent was transported by ambulance to and arrived there at 1922 hours. The initial history received by the E.R. staff was that the decedent had suffered some type of impact trauma from colliding with another person in the or that she had been struck in the chest with the struck. No evidence of external trauma was noted and thereafter eyewitnesses came to the hospital and provided the correct history of the decedent collapsing to the ground after

An admitting chest x-ray was taken at 1925 hours and was negative for any acute cardio-pulmonary findings. Another chest x-ray was obtained at 2020 hours and showed development of bilateral perihilar infiltrates. The impression at this time was that of pulmonary edema or aspiration. At 2050 hours a third chest x-ray revealed the onset of Adult Respiration Distress Syndrome. A cervical spine x-ray was negative. CAT scan of the head was negative for intracranial bleeding or mass effect.

The admitting EKG showed multifocal atrial tachycardia. Another EKG done on 4-7-98 revealed sinus tachycardia. The decedent's admitting potassium level was noted to be only 2.7. A urine drug screen was negative for Amphetamines, Barbiturates, Benzodiazepines, Cocaine, THC, Methadone, Methaqualone, Opiates, PCP and Propoxyphene.

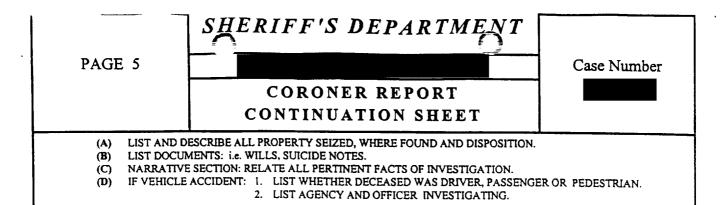
2. 知為致難體



The decedent's parents were notified by friends or adult staff at the to the hospital in the and were informed of the circumstances surrounding the sudden collapse of their daughter. Mr. spoke with this deputy at encountered several friends and teammates of his daughter in the waiting room. He began speaking with them in the context of finding out what had happened to his daughter. He related that he had been a many and was able to establish a quick rapport with these young people.

He eventually was told that his daughter was taking a product called "Ripped Fuel" and that it was for the purpose of making her a better Mr. told this deputy that he had absolutely no knowledge whatsoever that his daughter was taking any type of "drug" for athletic enhancement. He related that he had never heard of the product. He continued to inquire of the assembled young people about the product and was told that "everybody" was taking it. One young man related that everybody on was taking this substance and that it was common place for body builders and other sports minded people to take this product or similar products.

Mr. then asked the young man where the product could be obtained and the young man agreed to go with Mr. Upon arrival at the store, the young man pointed out the product on the shelf. The original intention of Mr. was to make a Xerox copy of the label for the emergency room physicians; however, the label would not copy very well so he purchased the bottle of 120 capsules for which he paid about \$30.00. He took the bottle of "Ripped Fuel" back to the hospital and showed the physicians the product and told them what he had been told by his daughter's friends and

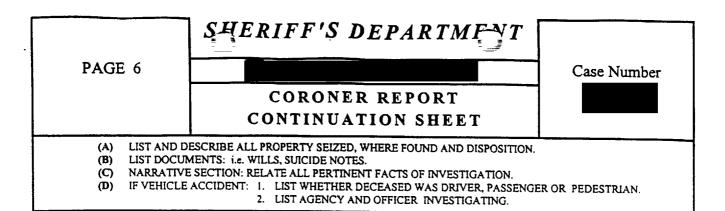


One of the attending physicians suggested that the decedent may be involved in the practice of bulimia. This suggestion was quickly put down by the parents and friends who related that the decedent never gulped down her food, always stayed at the table and never went to the bathroom immediately after eating. At times the decedent would eat only small portions or "pick" at her food, but she always ate something and "kept it down." On one occasion, Mr. related that he observed his daughter eating pizza with friends and that she "ate her share". She stayed at the table and continued to engage her friends in conversation. She did not get up and run to the bathroom. She never spoke of "bulimia" or expressed bulimic ideation. Mr. summed up his feelings about the possibility of bulimia in the context that "she is 15 years old and eats like a teenager".

At some point in the early examination and work-up of the decedent at the was summoned to the emergency room as an Internist to assist with the diagnosis and course of treatment for the decedent.

He goes on to state that that she has taken "her energy pills" referring to the "Ripped Fuel" capsules. He states that the number she has taken is unknown, however "stomach reveals probably at least 2-4 tablets were taken".

This deputy contacted Dr. by telephone and inquired of his statement about the number of "tablets" in the decedent's stomach. Apparently the decedent had been lavaged prior to his arrival in the emergency room and the contents that had been suctioned out were in a container adjacent to the decedent's bed. He looked at the material and observed the remains of a gelatin capsule and the semi-liquid material that he said looked "identical" to the capsules in the bottle of "Ripped Fuel" which the father had brought to the hospital.



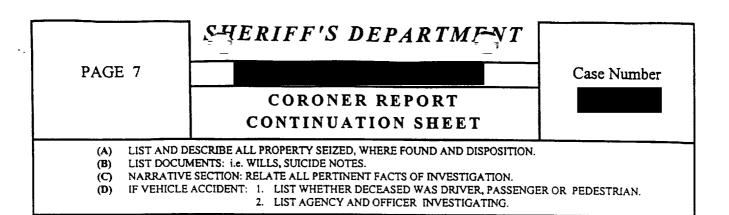
He stated that his estimate of the number of capsules taken by the decedent was strictly on an "eyeball" basis only and that it was his best guess based upon what he saw in the container. Very little food material was present in the gastric contents.

This deputy responded to on 4-10-98 and retrieved two blood samples obtained at the time of admission on 4-6-98 from the decedent. Unfortunately, all of the urine obtained at the time of admission as well as the stomach contents had been discarded after the patient was transferred to

The decedent's hospital course was one of increased respiratory distress and cerebral edema. On 4-9-98 a procedure was performed which revealed an absence of flow and uptake in the brain consistent with brain death. This procedure is a nuclear scan to show perfusion of the brain tissue. Thereafter it was noted by another physician that the decedent's brain had herniated and that her pupils were now fixed and dilated and non-reactive and that she met all the criteria for brain death. This determination was made at 1150 hours on 4-9-98.

This office authorized the procurement of the liver, pancreas and kidneys along with corneas. The heart and lungs were not authorized for transplant. An autopsy was conducted on 4-10-98. Examination of the heart revealed a massive myocardial infarction. The gross findings were consistent with an infarction of several days duration. The heart was retained for further examination and evaluation in conjunction with microscopic studies of cardiac tissue.

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Based upon the findings at autopsy, it was apparent that the decedent should have manifested symptoms of a "heart attack" at some point in time prior to the event on 4-6-98 at the Mr. was contacted and informed of the general findings at autopsy. He was asked if his daughter had experienced sudden onset of chest pain, shortness of breath, weakness, nausea, vomiting, tingling sensation in the left extremity or any other unusual feelings. Mr. stated that had never said anything to him or his wife in this regard. In his conversations with friends and family he had not been informed by anyone that had acted strange on any given day or that she had manifested any of the symptoms listed above. The only thing he could recall and that he had personal knowledge of was that one week before the incident on 4-6-98, had complained of a headache. She took some aspirin or Tylenol and the headache went away as usual.

Since my first interview with Mr. he has been talking to a lot of people and has not really developed any new facts or information relative to his daughter's use of "Ripped Fuel". A complete and thorough search of their home did not produce a bottle of "Ripped Fuel" nor did they find any loose capsules anywhere in the family home. There was nothing in her personal effects at school. No one has come forward with any information about when started taking "Ripped Fuel" and no one can provide any information about how many capsules she took or with what frequency she took them. Mr. stated that in his opinion the capsules were being distributed at school or in some other assembly of young people such as a sporting event, etc.

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Case Number

CORONER REPORT

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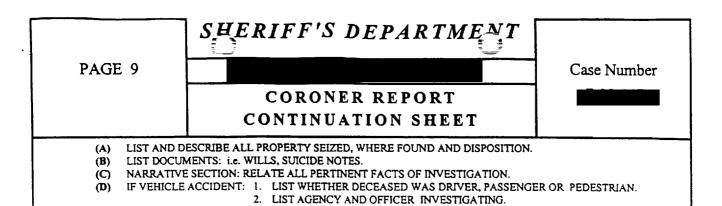
He stated that he was not suggesting that these capsules were being sold or distributed like controlled substances in an illegal manner; i.e., a "drug pusher" selling the capsules in a dark alley or some other sinister setting. He felt that there was a central location or person who doled out the capsules on request. It is noted that the capsules are somewhat prohibitive based on their cost and that it might be difficult for one person to purchase his or her private supply on a regular basis.

With respect to the product, the bottle of "Ripped Fuel" capsules purchased by Mr. was given to this deputy. As noted previously, the bottle contains 120 capsules. The label provides instructions and recommended use of the product. There are warnings about misuse of the product and that "improper use can be hazardous to your health". The recommended dose is no more than six (6) capsules per day, with two in the morning (before a workout) two in the afternoon and two in the evening before meals. At the bottom of the label there is the following statement in capital letters; "NOT INTENDED FOR USE BY PERSONS UNDER THE AGE OF 18".

As noted previously, this product is sold over the counter to anyone with the purchase price.

The product is not a controlled substance in the context of the Health and Safety Code of the State of i.e., a "narcotic" or other drug identified in of this Code. Unlike alcohol or tobacco products, there is no actual age requirement, albeit there is the disclaimer that it is not intended for use by persons under 18 years of age.

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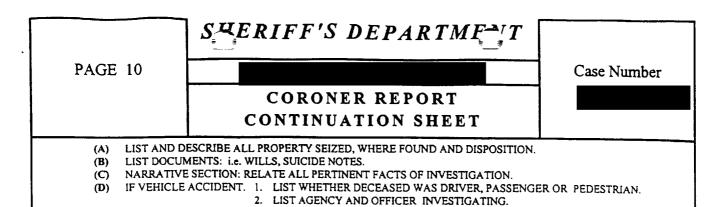


In pursuit of further information about the product "Ripped Fuel" and or its ingredients, this deputy contacted the Poison Control Center in at their "800" telephone number listed in the local directory. I spoke with Dr. who informed me that their office had received a call from the on 4-6-98 regarding the product, "Ripped Fuel". Dr. related that their agency had received previous complaints concerning the "drug", Ephedrine and products similar to "Ripped Fuel".

She related that there was concern about Ephedrine and the adverse effects of this drug on the heart. She also related that Ephedrine can cause increased heart rate, hypertension and myocardial infarction. According to Dr. it wasn't that the Ephedrine was necessarily in toxic levels, causing these problems, but that the drug exerted specific effects upon cardiac tissue resulting in the problems mentioned above. Dr. stated that the Poison Control agency would be following this case and would work in conjunction with personnel at the Food and Drug Administration in that regard. This office was also contacted by Dr. of the Poison Control Center in as well as Dr. of the Dept. of Health Services, Food & Drug Agency,

This deputy contacted Mr. Bill Bowman, the local FDA Representative. He stated that his office was also aware of this case and that he would pass on information about the case to Washington and have someone at the main FDA office contact me. Dr. Lori Love, MD, Ph.D., contacted this deputy regarding this case.

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She reiterated some of the basic information that Dr. and provided and related that the FDA had a large data base of information concerning Ephedrine related products. Dr. Love also stated that she would send selected articles and information contained in the literature about Ephedrine related products and cases wherein people had experienced specific complaints.

As a result of this death, the news media also became very involved in calling this office seeking information about the cause of death, the connection of the product "Ripped Fuel" and if the death was due to Ephedrine. In speaking with the news media, a case in was alluded to and in this regard Dr. Love was again contacted by Department Through Dr. Love, a contact at the Office of the Chief Medical Examiner in was provided. Dr. Love had already contacted the staff at that office and had obtained their assurance that they would assist this office any way they could. It was decided that the decedent's cardiac tissue and blood specimens would be sent to the Medical Examiner Office in for their evaluation and consultation in this case.

Final determination of a cause of death in this case and a final classification of this death is pending as of the writing of this report on 4-20-98. Additional research and inquiry will be made on any other cases in any other jurisdiction that appear to be similar in nature to the death of

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PAGE 11 Case Number CORONER REPORT CONTINUATION SHEET (A) LIST AND DESCRIBE ALL PROPERTY SEIZED, WHERE FOUND AND DISPOSITION. (B) LIST DOCUMENTS: i.e. WILLS, SUICIDE NOTES. (C) NARRATIVE SECTION: RELATE ALL PERTINENT FACTS OF INVESTIGATION. (D) IF VEHICLE ACCIDENT: 1. LIST WHETHER DECEASED WAS DRIVER, PASSENGER OR PEDESTRIAN. 2. LIST AGENCY AND OFFICER INVESTIGATING.

Addendum of 4-21-98 by

Mr. called this office this date and spoke with Deputy regarding new information he had just developed, regarding his daughter's use of "Ripped Fuel". Mr. stated that family members had been cleaning out some of his daughter's effects in her bedroom closet. They found a cardboard box containing assorted personal items and a small plastic box which contained one capsule. Mr related that the capsule looked just like the "Ripped Fuel" capsules he had purchased on 4-6-98 at the Mr. stated that he would retain this capsule in his possession until it could be delivered to this office or be picked up by a representative of this office.

Mr. also added that he had been speaking with a close personal friend of the past several days and that he had learned from this person that might have started taking the "Ripped Fuel" product about two or three weeks before her collapse on 4-6-98 in According to the informant, both she and were at the week were at the mentioned the "Ripped Fuel" capsules or related that she was taking them.

Mr. was going to re-contact this informant and determine if she was willing to call this deputy or if this deputy could contact her and interview her directly regarding her knowledge of use of "Ripped Fuel".

Investigation will continue with regards to these new developments. An addendum will be added when any new information is obtained, from any source.

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PAGE 12 Case Number CORONER REPORT CONTINUATION SHEET (A) LIST AND DESCRIBE ALL PROPERTY SEIZED, WHERE FOUND AND DISPOSITION. LIST DOCUMENTS: i.e. WILLS, SUICIDE NOTES. (C) NARRATIVE SECTION: RELATE ALL PERTINENT FACTS OF INVESTIGATION. (D) IF VEHICLE ACCIDENT: 1. LIST WHETHER DECEASED WAS DRIVER, PASSENGER OR PEDESTRIAN. 2. LIST AGENCY AND OFFICER INVESTIGATING.

Addendum of 7-16-98 by

On this date the decedent's heart, which was sent to the Medical Examiner's Office in was returned to the pathology department along with a written report. The report was prepared by MD and is dated 06/26/98. Apparently Dr. is an associate medical examiner with the Chief Medical Examiner's Office. She is also a staff member of the department of pathology of the Teaching Affiliate of the When the heart was received by the Medical Examiner's Office, Dr. involved in the consultation along with Dr. The heart was essentially turned over to for examination. The final diagnosis listed on the report of Dr Dr. and Dr. as follows:

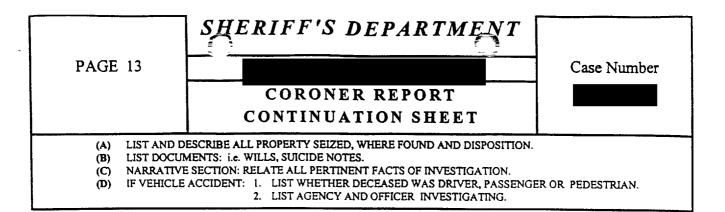
Extensive remote ischemic myocardial damage in the distribution of the left coronary circulation.

Anterior left ventricular wall thinning.

Extensive subendocardial myocyte vacuolization.

Multifocal acute and healing myocardial injury.

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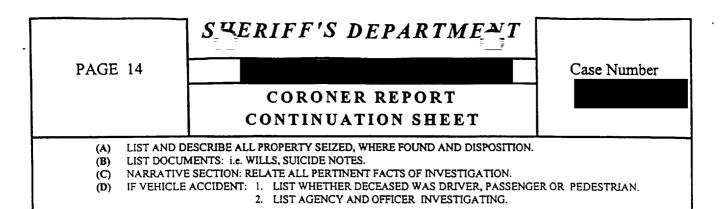


The above diagnosis and information is the same information supplied to the coroner's pathologist on June 3, 1998, during a telephonic contact with Dr. On page two of the report, Dr. nakes the following comment in paragraph three: "In the context of the possible ingestion of an ephedrine containing substance, such as "Ripped Fuel", it is impossible to distinguish morphologically whether the sudden collapse and subsequent death were due purely to the events of the aberrant coronary arterial anatomy or whether factors such as exercise or the presence of sympathomimetic substances were necessary contributors". (Emphasis Added)

Also on page two of the report in the second paragraph is the following statement by Dr.

	. This information is
in complete conformity with the facts released by this Office in a news release on June 4, 1998.	

It is the contention of this Office that the decedent died as a direct result of her cardiac anomaly described above. It is also our contention that we cannot prove whether or not the decedent was using "Ripped Fuel" or some other ephedrine based product at the time of her death. This fact is demonstrated by the absence of any toxicological evidence of ephedrine in her system. (Stomach contents from the decedent in the emergency room at were not tested and not available for testing by this agency.) Gas Chromatograph/Mass Spectrometry by this agency on blood obtained at the time of admission at was negative for the presence of ephedrine. Additionally, no one, including family members, has provided a statement to this deputy clearly stating that they saw the decedent take "Ripped Fuel" or some other product on the day she collapsed or at any other time.

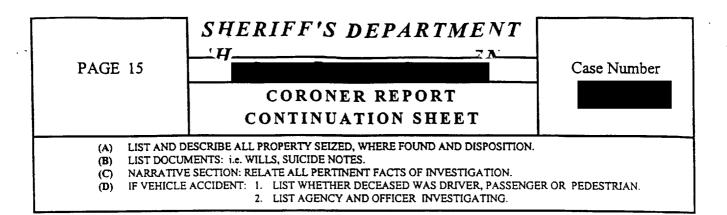


There is a strong suggestion or argument that she was taking the product based upon statements of her friends and the fact that her father did find a capsule of apparent "Ripped Fuel" in her closet while cleaning out her room. Unfortunately, this is not "proof" that the decedent was taking "Ripped Fuel" or any other ephedrine based product. It is obvious that based upon the information about ephedrine based products, there can be adverse effects upon the heart due to abuse of these products. If a person who has a cardiac anomaly such as the takes ephedrine based products, it could aggravate or exacerbate the pre-existing condition. Both Dr. and this Office have clearly stated that this determination cannot be made with regards to the death of

In my original report on page six, in the last paragraph, I state that initial autopsy findings revealed a "massive myocardial infarction". Our news release also alluded to a "massive heart attack of 1-week to ten days" duration. This information was based upon gross findings only and not microscopic examination. It was a "guess-timate" based upon visual examination only. Once microscopic examination was done here as well as by Dr. it was readily apparent that the "heart attack" was of various stages of development. Dr. described "myocardial injury of at least 3 ages; acute, healing and remote". In the case of the "remote" heart attack or myocardial injury, this event could have occurred years ago while the decedent was in her infancy.

In this context, the question posed to her parents about recent symptoms or unusual behavior, etc. was most likely unanswerable. The decedent could have experienced this event while asleep or when she was so young that she could not express herself to her parents. This is damage to the heart that is described in the literature.

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The textbook, Cardiac Pathology An Integrated Text and Color Atlas, Raven Press, N.Y.

1982 at Plate 16.4 states the following: "If patients with this lesion survive infancy, collateral supply from the right coronary artery produces a coronary "steal" potential which can lead to further myocardial ischemia and infarction. Ischemia and infarction are also produced during the initial critical period, and at this stage they are either fatal or compensation occurs". The text continues on to state: "However, in patients who do survive the critical neonatal period, these subsequent changes can produce the trigger for sudden death during adolescence".

In any event, when the "remote" heart attack occurred, the decedent obviously survived and her heart compensated for the damage. As noted in the preceding paragraph, the damaged heart can then "produce the trigger for sudden death during adolescence". It is this mechanism which is believed to have occurred in this case causing a new or "acute" heart attack to occur while the decedent was playing soccer.

On June 16, 1998 an amended death certificate will be filed for the decedent which will state
that the cause of death is Syndrome of Myocardial Ischemia due to;
This death will be classified as due to natural causes.

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CORONER REPORT

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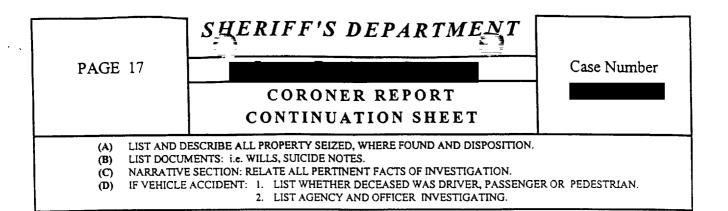
Addendum of 7-23-98 by

The decedent's heart was received at on June 16, 1998, after being sent by FedEx on June 15, 1998. This deputy opened the sealed container and found the heart tissue along with the original report of Dr. No blood samples were present.

It was confirmed at this office that the samples were released to this deputy on 4-21-98 and Mr. Physician's Assistant in Pathology, confirmed that he had sent the blood samples to In reading the report of Drames no mention is made of the blood samples and there was no separate toxicology report submitted.

After several inquires to the Medical Examiner's Office were made by this deputy, a telephone call was received from Dr. on Thursday, July 23, 1998 at 0938 hours. Dr. stated that the contents of both vials of blood had been used by his Office in an attempt to determine the presence of ephedrine. He stated that no ephedrine was detected in the analyses performed by his Office. Dr. also stated that the empty vials had been discarded by his laboratory in a routine manner in that no blood was left.

Dr. related that there was a very small amount of blood in either vial and that the total quantity received by them was insufficient to conduct the various tests and analyses that they had considered doing. Once the vials were empty, the laboratory staff routinely threw them away as they were no longer of any value. (This deputy's recollection of the amount of blood was that there was only a few cc's aggregate between the two vials; I would estimate that maybe 3 or 4 cc total was sent to the Medical Examiner's Office.)



After the telephonic communication on June 3, with Dr. it was believed that the heart tissue and blood samples were en route back to After several days and then weeks passed by, numerous calls were made to the Medical Examiner Office in an attempt to find out why the tissue and samples had not been received. As noted above, the heart tissue was finally received on July 16th.

Upon receipt of the heart tissue and the report of Dr. the decedent's father was notified and the contents of the report were read to him. He was also told at that time that the blood samples were not returned and that there was no mention of the samples in the report and no explanation as to the disposition of samples. Mr. was concerned about the heart tissue and blood samples from the onset of this case and had made several requests of this deputy and of this Office that the heart tissue and blood samples be retained for future review, evaluation and analysis.

This addendum is for the purpose of explaining the disposition of the blood samples of which had been obtained from the on 4-10-98. The explanation of Dr. that the total amount of blood received by their Office was used for testing and that <u>no</u> blood was left has to be accepted in lieu of the samples being returned with the heart tissue.

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AUTOPSY REPORT

Autopsy No:	Date of Autopsy:	April 10, 1998
Name:	Age: <u>15</u>	Sex: <u>Female</u>
Place of Autopsy:		
Name of Pathologist:	M.D.	

DIAGNOSES

I. with:

- A. Myocardial ischemia, chronic.
- B. Myocardial infarct, organized, in distribution of left coronary artery.
- C. Sudden cardiopulmonary arrest, anamnestic.
- D. Status post resuscitation, with:
 - 1. Survival for approximately three days.
 - 2. Status post placement of right inguinal arterial line with thrombosis of right iliac artery and gangrene of right leg.
 - 3. ARDS.
 - 4. Acute myocardial ischemia, subendocardial distribution.
 - 5. Bronchopneumonia.
- II. Use of Ephedrine containing dietary supplement, anamnestic.

CAUSE OF DEATH:

SYNDROME OF MYOCARDIAL ISCHEMIA DUE TO

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The autopsy is performed in the morgue on Friday, 10 April 1998 at 1230 with Deputy Coroner of the and in attendance.

ristory: This 15-year old Hispanic female while collapsed. She was down approximately 30-45 minutes. Resuscitation attempts were made and she was transported to the local hospital. After stabilization she was transported to the at while in a right inguinal arterial line was placed resulting in thrombosis of the right iliac artery and gangrene of the right lower leg. She developed adult respiratory distress syndrome. She never improved and died three days after admission.

external examination: This is the unembalmed body of a well developed, well nourished Hispanic female appearing the stated age of 15 years. An endotracheal tube is in the mouth and a catheter enters the left inguinal region. The right side of the chest contains two transverse therapeutic incisions measuring 20 and 50 mm long, the longer of which is partially closed with sutures. The right inguinal region contains a sutured 100 mm long vertical surgical incision. The right medial calf contains a 130 mm long full thickness incision of the skin revealing dusky red ischemic-looking musculature. There are therapeutic needle punctures of the antecubital fossae. The midline of the chest and abdomen contains a sutured surgical incision extending from the suprasternal notch to the symphysis pubis. The incision was placed for harvesting of organs.

The head is atraumatic and the scalp is covered by long brown hair. The cornea have been harvested. The nose and ears are unremarkable. Each earlobe is pierced once. The nose contains tan mucoid material and there is a 6 mm superficial erosion along the edge of the left nostril. In addition to the endotracheal tube, the mouth contains a small quantity of tan pasty material and teeth in good repair. The neck and chest are symmetric and the abdomen is level with the chest plane. External genitalia are mildly edematous. The upper extremities show no additional alteration. The lower extremities are symmetrical. There is purple gangrene extending from the right mid-tibial area distally to involve the entire right ankle and foot which is swollen. The left leg has a normal configuration without edema or other alteration.

INTERNAL EXAMINATION: The pancreas, kidneys, and liver have been previously harvested. The pleural cavities each contain bloody fluid without exudate or other alteration. The mediastinum is in the midline.

RESPIRATORY SYSTEM: The left lung is 450 gm, the right lung 500 gm. The pleural surfaces have a variegated dark red to purplered appearance and are glistening. The lung parenchyma is
essentially non-crepitant with extensive areas of light and dark
red consolidation on a background of homogeneous brick red lung
parenchyma. Approximately 40-50% of each lung appears
consolidated and involves all lobes. The pulmonary arteries are
free of thrombi and the bronchial tree contains a small quantity
of thick blood-tinged mucus.

CARDIOVASCULAR SYSTEM: The epicardium is transparent and glistening. The heart has a prominent right ventricle and weighs 300 gram. The foramen ovale is anatomically closed. endocardium of the right and left ventricles are transparent and glistening. The annuli of the tricuspid and pulmonary valves appear dilated. The right ventricle appears dilated and the free wall averages 4 mm in thickness. The left ventricle has a normal configuration and the walls are up to 15 mm thick. The endocardium is glistening and contains irregular areas of myocardial fibrosis. The mitral valve has a normal configuration with thin and delicate chordae tendineae. The aortic valve is well formed, but appears mildly dilated. There are a few atherosclerotic plaques along the base of the aortic root. Sections through the myocardium of the left ventricle reveal extensive myocardial scarring involving the anterior wall with focal transmural extension. The transmural portion of the infarct results in a concavity of the anterior left ventricular wall with thinning to 3 mm. Myocardial fibrosis, though not transmural, is also present at the anterolateral left ventricular free wall, anterior septum and the left ventricular papillary muscles in a patchy multifocal distribution. The left ventricular subendocardium reveals a poorly circumscribed zone of variegated pallor consistent with subendocardial infarction. epicardial arteries have a right dominant distribution.

Refer to cardiopathology consultation report for further description and discussion of this congenital anomaly.

The aorta has been partially harvested and the remaining portion contains a few fatty streaks. Dissection of the right iliac artery reveals a suture line with no evidence of residual occlusion.

HEMIC AND LYMPHATIC SYSTEM: A portion of spleen remains in the body weighing 60 gm. The capsule is smooth and purple-red and the parenchyma is homogeneous, firm and congested. Lymph nodes appear within normal limits.

GASTROINTESTINAL SYSTEM: The esophagus, stomach, small intestine and large intestine, aside from mild edema and gaseous distention, are without other alteration. The liver and pancreas have been harvested.

GENITOURINARY SYSTEM: The kidneys have been harvested. The urinary bladder is without dilatation. The internal genitalia have a normal configuration without alteration.

ENDOCRINE SYSTEM: The adrenal glands are not identified.

CENTRAL NERVOUS SYSTEM: The scalp is free of contusion or laceration. The calvarium is intact and the dura and leptomeninges are without hemorrhage or exudate. The leptomeninges are transparent, glistening and severely congested. The enlarged, diffusely edematous brain weighs 1,475 gm. The cerebrovasculature is without alteration. There is coning of the cerebellar tonsils, grooving of the uncinate gyri, and diffuse flattening of the cerebral gyri. The brain has a soft consistency. Coronal sections reveal generalized edema without focal alteration. There is no evidence of focal malacia or hemorrhage. Cerebrospinal fluid is non-hemorrhagic and is clear.

NOTE: Stock tissue saved - microscopics submitted. Blood is obtained from and submitted for Toxicology.

04/10/98 D 04/13/98 T

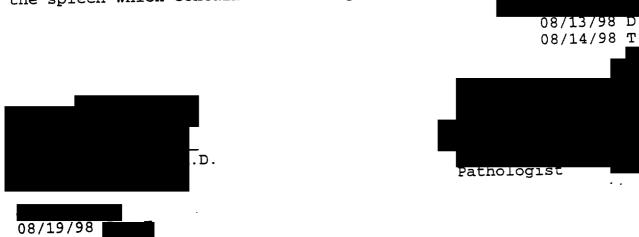
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MICROSCOPIC SUMMARY

RESPIRATORY SYSTEM: Sections of lung exhibit diffuse alveolar damage consisting of hyaline membranes lining alveoli, reactive alveolar lining cells and alveolar spaces filled with proteinaceous precipitate, histiocytes and a mild to focally moderate polymorphonuclear leukocyte infiltrate. Occasional bronchioles contain neutrophils within the lumens which pour into the adjacent parenchyma. There is also a field of superimposed hemorrhage.

CARDIOVASCULAR SYSTEM: Multiple sections of left ventricle reveal areas of subendocardial and focally transmural myocardial infarct scarring which is occasionally dense. In all sections there is acute subendocardial infarction consisting of hypereosinophilic fibers and areas of contraction band necrosiswithout an inflammatory infiltrate. In one section, the infarction extends transmurally. The remaining myocardium contains patchy areas of interstitial fibrosis and fields of hypertrophied fibers containing large rectangular, hyperchromatic nuclei. The endocardium is focally thickened by fibrosis. There are occasional stenotic large and small mural coronary arteries due to severe fibrous thickening of the walls. The most severely involved vessels are within a section of the interventricular septum where there is also acute and chronic subendocardial. ischemia. All cardiac sections contain chronic subendocardial ischemia associated with the acute ischemic change and consisting of myocytolytic fibers.

HEMIC AND LYMPHATIC SYSTEM: There is severe acute congestion of the spleen which contains normal organized lymphoid tissue.



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AUTOPSY REPORT

BIRTH DATE	SEX/AGE F	RACE/ETHNIC	ACCESSION NUMBER
DEATH 04/09/98	AUTOPSY 05/01/98 11:53 AM	INTERVAL 22 DAYS	HOSPITAL LOCATION MEDICAL EXAMINER'S,
MEDICAL EXAMINER	PERMISSION	RESTRICTIONS HEART ONLY	REPORT DATE 06/26/98
PHYSICIAN: DR.			
PROSECTOR: DR		STAFF: DR.	

FINAL ANATOMIC DIAGNOSES

CONSULT HEART RECEIVED FROM THE MEDICAL EXAMINER'S OFFICE,

Extensive remote ischemic myocardial damage in the distribution of the left coronary circulation.

Anterior left ventricular wall thinning.

Extensive subendocardial myocyte vacuolization.

Multifocal acute and healing myocardial injury.

COMMENT:

The decedent was a 15 year old Hispanic girl who collapsed after

She was taken to the hospital where she deteriorated over three days and developed adult respiratory distress syndrome. Brain death was established and life support systems were withdrawn. There was a history of possible use of the metabolic enhancer, "Ripped Fuel". The heart, received in consultation from the in (which had received the heart in consultation from 300 grams, and had been extensively cut prior to this analysis with the epicardial vessels opened longitudinally. One transverse section had been stained with triphenyl tetrazolium chloride (TTC).

The pericardial surface was smooth and glistening with no adhesions or contusions.

The left main

coronary artery gave rise to the left circumflex and left anterior descending coronary arteries, the distribution of which was normal. The right coronary ostium was normally located on the aorta, and the distribution of the coronary artery was normal and dominant. There was no evidence of atherosclerotic

(continued on following page)

FINAL ANATOMIC DIAGNOSES (cont'd)

change or thrombosis. Examination of the TTC stained slice revealed a white, glistening, transmural scar, 2 x 1.3 cm on the anterior aspect, where there was thinning of the anterior left ventricle to 0.3 cm (nl 0.9 to 1.5 cm). Other regions of left ventricular free wall measured up to 1.4 cm in thickness. The lateral left ventricle showed a subendocardial brown discoloration in a 2.2 x 0.6 cm area, consistent with recent injury. The left ventricular papillary muscle and multifocal areas on the anterolateral aspect also showed a brown color measuring up to 0.7 x 0.6 cm. The remainder of the heart (not TCC stained) showed multiple areas of fibrosis in the high anterior septum and the posterior septum, measuring up to 0.8 by 0.8 cm. The septum and right ventricle measured 1.2 cm and 0.45 cm in thickness, respectively. Microscopically, there were extensive areas of scarring consistent with remote ischemic injury, corresponding to the grossly evident fibrosis on the TTC stained section. In the anterior septal region, there was healing myocardial injury, consistent with a duration of 2-3 weeks. In the left ventricle, there was extensive subendocardial myocyte vacuolization, areas of fresh coaqulation necrosis and microscopic foci of necrosis with contraction bands. There was no evidence of myocarditis or vasculitis.

associated with high mortality and uncommon survival past childhood without surgical correction. Longer survival is associated with a decreased extent of distribution of the left coronary system and increased collateral formation to supply the left side of the heart with oxygenated blood.

This 15 year old girl suffered a sudden collapse, and died after 3 days in hospital had collectively extensive myocardial injury of at least 3 ages; acute, healing and remote. The extensive anterolateral left ventricular scarring correlated in location with the expected findings in also found to have multiple foci of coagulation and contraction band necrosis, suggestive of a recent myocardial injury, likely less than 3 days in duration and consistent with resuscitation from a collapse and possibly inotropic therapy. However, there is large variation in the morphological features of healing microinfarcts, and it is possible that this injury may predate the sudden collapse. Moreover, the healing injury of several weeks duration could also have provided an arrhythmogenic focus. In the context of the possible ingestion of an ephedrine containing substance, such as "Ripped Fuel", it is impossible to distinguish morphologically whether the sudden collapse and subsequent death were due purely to the events of aberrant coronary arterial anatomy or whether factors such as exercise or the presence of sympatomimetic substances were necessary contributors.

REFERENCES:

Gouley BA

Ogden JA. Congenital anomalies of the coronary arteries. American Journal of

(continued on following page)

FINAL ANATOMIC DIAGNOSES (cont'd)

Cardiology (1970) 25:474.

Cowan MJ, Reichenbach D, Turner P, Thostenson C. Cellular response of the evolving myocardial infarction after therapeutic coronary artery reperfusion. Human Pathology (1991) 22:154-63.

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MICROSCOPIC DESCRIPTION

Histology key:

- 1-posterior left ventricle, papillary muscle
- 2-lateral left ventricle
- 3-anterior left ventricle

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- 4-anterior septum
- 5-posterior septum
- 6-right ventricle

Microscopically, there were extensive areas of scarring consistent with remote ischemic injury, corresponding to the grossly evident fibrosis on the TTC stained section. In the anterior septal region, there was healing myocardial injury, consistent with a duration of 2-3 weeks. In the left ventricle, there were extensive subendocardial myocyte vacuolization, areas of coagulation necrosis and microscopic foci of contraction band necrosis consistent with acute injury of approximately 2-4 days duration. There was no evidence of myocarditis or vasculitis.

CLINICAL SUMMARY

The decedent was a 15 year old Hispanic girl who collapsed after

She was taken to the hospital where she deteriorated over three days and developed Adult Respiratory Distress Syndrome. Brain death was established and life support systems were withdrawn. There was a history of possible use of the metabolic enhancer, "Ripped Fuel".

M.D.

PROSECTOR
Signed by 06/06/98

SENIOR PATHOLOGIST Signed by 06/26/98

Memorandum to ARMS # 12843

Date: Original dated 9/30/98

Updated 6/8/99 and 6/14/99

From:

Medical Officer, Clinical Research and Review Staff, Office of Special

Nutritionals, HFS-452

Subject:

Medical Records Place in Permanent Storage.

The following types and amounts of records (more than 20 pages total) were place in permanent storage on this date because they were not considered essential for interpretation of this adverse event.

Approx Pages	Type of Records
Total: 46	Nursing notes
l	Dietitian notes/Social Worker
5	Respiratory therapy/occupational therapy/physical therapy notes
	Clergy notes
	Medication records
35	Physician's orders
3	Vital signs, fluids, input/output records
	Ventilator records
Tothe: 4	Hospital administrative records (e.g., insurance information, living will, etc)
6	Blood bank records
	Requisition
	0

Originally S. Nawaz Updates by S. Dua & N. Elifman